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United States District Court,D. New Jersey.

WARNER LAMBERT CO., Plaintiff,

v.

PUREPAC PHARMACEUTICAL CO. and Faulding Inc., Defendants.

PUREPAC PHARMACEUTICAL CO. and Faulding Inc., Plaintiffs,

v.

WARNER LAMBERT CO. and Godecke Aktiengesellschaft, Defendants.

No. Civ.A. 98-02749(JCL), Civ.A. 99-05948(JCL), Civ.A. 00-02053(JCL).

Dec. 22, 2000.

John J. Francis, Jr., Drinker, Biddle & Reath, Florham Park, NJ, for plaintiff.

Arnold B. Calmann, Saiber, Schlesinger, Satz & Goldstein, Esqs., Newark, NJ, for defendants.

OPINION

LIFLAND, J.

***1** Presently before the Court are the following three motions in cases involving Plaintiff Warner Lambert Co. ("Warner-Lambert") and Defendants Purepac Pharmaceutical Co. and Faulding Inc. (collectively referred to as "Purepac").

Docket No. 99-05948: Warner-Lambert moves, pursuant to Rule 12(b)(6), to dismiss Purepac's counterclaims alleging antitrust violations and unfair competition. That motion will be denied.

Docket No. 98-02749: Warner-Lambert moves for partial summary judgment dismissing Purepac's counterclaim alleging unfair competition, and in the alternative, Warner-Lambert moves to bifurcate the patent infringement claims from the unfair competition claims. That motion will be denied in part and granted in part.

Docket No. 00-02053: Warner-Lambert moves to dismiss Purepac's complaint which seeks a declaratory judgment of non-infringement. That motion will be granted.

BACKGROUND

A. First Lawsuit (98-2749):

The following facts are undisputed unless otherwise noted. Warner-Lambert discovered gabapentin in the mid-1970's. Warner-Lambert learned that gabapentin was useful in preventing and limiting epileptic seizures. In 1979, Warner-Lambert obtained U.S. Patent No. 4,087,544 (" '544 patent") covering the use of gabapentin to treat epilepsy. That patent expired on January 16, 2000.

On January 15, 1992, Warner-Lambert submitted a New Drug Application ("NDA") to the FDA for the use of gabapentin to treat epilepsy. On December 30, 1993, the FDA approved the NDA. According to the FDA's required labeling, gabapentin is useful for "adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy." The tradename used by Warner-Lambert for gabapentin is Neurontin.

In the late 1980's, Warner-Lambert discovered that gabapentin could be useful in slowing or preventing neurodegeneration. On January 28, 1992, Warner-Lambert received U.S. Patent No. 5,084,479 (" '479 patent") claiming the use of gabapentin to treat neurodegenerative diseases. That patent expires on January 2.2010. The '479 patent's dependent claims describe a method wherein the neurodegenerative disease is stroke, Alzheimer's disease, Huntington's disease, Amyotrophic Lateral Sclerosis (A.L.S.), and Parkinson's disease.

Before the late 1980's, gabapentin was known to exist in two principal forms: (1) an anhydrous form where no water is associated with the gabapentin molecules and (2) a hydrated form where some water is associated with the gabapentin molecules. Only two hydrated forms were known: (1) two gabapentin molecules associated with each molecule of water and (2) four gabapentin molecules associated with each molecule of water.

In the late 1980's, two of Warner-Lambert's chemists discovered a new, previously-unknown form, where each gabapentin molecule is associated with one molecule of water. This monohydrate is very

crystalline and could be purified to a high degree. After purification, the monohydrate can be readily converted back to the anhydrous form, containing no water. Warner-Lambert received U.S. Patent No. 4,894,476 (" '476 patent") on January 16, 1990 claiming the new monohydrate. The '476 patent expires on May 2, 2008.

***2** In early 1994, after receiving FDA approval for the use of gabapentin to treat epilepsy, Warner-Lambert began marketing gabapentin under the Neurontin label. Doctors also began to use Neurontin to treat neurodegenerative conditions such as Parkinson's disease, A.L.S. and neuropathic pain, even though it had not been approved by the FDA for such use. Increased awareness of these other uses of Neurontin led to significant sales for non-epilepsy uses. Today, more than 78% of Neurontin prescriptions are written for indications other than epilepsy, including the treatment of neuropathic pain and neurodegenerative diseases.

In the middle of 1997, Purepac began to look at the feasibility of selling a generic version of Neurontin. In conducting its feasibility studies, Purepac contacted two gabapentin suppliers. Plantex and Recon. Purepac settled on Plantex and the samples used to support its eventual application to the FDA were made with Plantex gabapentin.

On March 30, 1998, after completing work on its generic gabapentin. Purepac submitted its Abbreviated New Drug Application to the FDA. With this submission, Purepac was required to certify as to each patent covering gabapentin, which are listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"). The Orange Book contains all the patents that a pioneer manufacturer listed on its NDA to the FDA. As to Warner-Lambert's '544 patent (use of gabapentin to treat epilepsy). Purepac certified that it did not intend to market its generic gabapentin until that patent expired. Purepac also certified that Warner-Lambert's '476 gabapentin monohydrate patent would not be infringed by Purepac's manufacture and sale of generic gabapentin. Purepac did not certify as to Warner-Lambert's '479 patent (use of gabapentin to treat neuro-degenerative diseases). Alternatively, Purepac filed a statement of "inapplicable use."

After its certifications to the FDA. Purepac sent notice to Warner-Lambert. The Notice was received on June 1, 1998, and informed Warner-Lambert of Purepac's position regarding the '476 monohydrate patent. On July 14, 1998, Warner-Lambert brought this action alleging infringement of the '476 and '479 patents.

Purepac moved for summary judgment. On August 25, 1999, this Court denied the motion due to unresolved discovery issues surrounding the '476 patent and due to genuine issues of material fact as to whether Purepac would knowingly and actively induce infringement of the '479 patent.

B. Second Lawsuit (99-5948):

Purepac filed a subsequent Abbreviated New Drug Application with the FDA for a generic version of gabapentin in tablet form as opposed to the capsule form involved in 98-2749. Thereafter, Purepac certified that Warner-Lambert's '476 gabapentin monohydrate patent would not be infringed by Purepac's manufacture and sale of generic gabapentin.. After receiving notice on November 8, 1999, Warner-Lambert brought this second action against Purepac, also alleging infringement of the '476 and '479 patents.

***3** Purepac filed counterclaims against Warner-Lambert alleging, in pertinent part, violation of the antitrust laws and unfair competition. The counterclaims allege the following facts: Warner-Lambert fraudulently listed the '476 and '479 patents in the NDA to the FDA for approval of gabapentin anhydrous, under the brand name Neurontin. By listing these patents in the NDA, Warner-Lambert forced the FDA to include the patents in the Orange Book. Any generic gabapentin manufacturer is prevented from applying for an ANDA without listing the patents contained in the Orange Book and giving notice to the patent holder. Once the required notice is given, the pioneer manufacturer has immediate authorization to institute infringement litigation even though the ANDA claims that there is no infringement. According to Purepac, Warner-Lambert listed the '476 patent even though the gabapentin monohydrate covered by the '476 patent was not used at any point during the production of Neurontin. The counterclaim further alleges that Warner-Lambert should not have listed the '479 patent because the labeling authorization for Neurontin permits treatment only for illnesses related to epilepsy.

Purepac contends that subsequent to this Court's denial of summary judgement in 98-2749, the capsule litigation, discovery has revealed that Purepac's form

of gabapentin does not contain gabapentin monohydrate, thereby negating any possible infringement of the '476 patent.

C. Litigation Surrounding Patent '482 (00-2053 and 00-2931):

On April 25, 2000, Warner-Lambert was issued Patent 6,054,482 (" '482 patent") for "Lactam-Free Amino Acids." This patent covers gabapentin formulas which are low in lactam impurities. Purepac alleges that Warner-Lambert threatened to sue Purepac for infringement of the '482 patent based on the earlier ANDA applications to market generic gabapentin capsules and tablets.

There is a factual dispute as to the actual point at which the '482 patent was listed in the FDA Orange Book. The record indicates that Warner-Lambert submitted the '482 patent information to the FDA on April 25, 2000 via telecopier. However, Purepac provides the Declaration of Arona Same stating that she was unable to find the '482 patent listed in the Orange Book until May 16, 2000. On April 28, 2000 Purepac filed suit in this court seeking a declaratory judgment of non-infringement and invalidity of the '482 patent. *Purepac v. Warner-Lambert,* No. 00-02053(JCL). After locating the '482 patent in the Orange Book, Purepac amended its ANDA applications for both gabapentin tablets and capsules to include Paragraph IV certifications that Purepac's products do not infringe upon the '482 patent. The record indicates that Warner-Lambert received official notice of the Paragraph IV certifications on June 14, 2000. On August 28, 2000 Warner-Lambert filed a motion in this court to dismiss Purepac's complaint for lack of subject matter jurisdiction under Rule 12(b)(1) and for failure to state a claim under Rule 12(b)(6).

***4** On July 15, 2000, Warner-Lambert filed a complaint against Purepac in this Court alleging infringement of the '482 patent. *Warner-Lambert v. Purepac,* No. 00-02931(JCL).

I. Warner-Lambert's Motion to Dismiss Purepac's Counterclaims of Antitrust Violations in Docket No. 99-05948.

STANDARD OF REVIEW

A. Motion to Dismiss under 12(b)(6):

In deciding a motion to dismiss a counterclaim under Federal Rule of Civil Procedure 12(b)(6), all allegations in the counterclaim must be taken as true and viewed in the light most favorable to the counterclaimant. *See Warth v. Seldin,* 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975); *Trump Hotels & Casino Resorts, Inc., v. Mirage Resorts Inc.*, 140 F.3d 478, 483 (3d Cir.1998); *Robb v. Philadelphia,* 733 F.2d 286, 290 (3d Cir.1984). A court may consider only the counterclaim, exhibits attached to the counterclaim, matters of public record, and undisputedly authentic documents if the counterclaims are based upon those documents. *See Pension Benefit Guar. Corp. v. White Consol., Indus.,* 998 F.2d 1192, 1196 (3d Cir.1993). If, after viewing the allegations in the light most favorable to the counterclaimant, it appears beyond doubt that no relief could be granted "under any set of facts which could prove consistent with the allegations," a court shall dismiss a counterclaim for failure to state a claim. *Hishon v. King & Spalding,* 467 U.S. 69, 73, 104 S.Ct. 2229, 81 L.Ed.2d 59 (1984); *Zynn v. O'Donnell,* 688 F.2d 940, 941 (3d Cir.1982).

Furthermore, "[I]n antitrust cases, where 'the proof is largely in the hands of the alleged conspirators.' dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." *Hospital Building Co. v. Trustees of Rex Hospital,* 425 U.S. 738, 746, 96 S.Ct. 1848, 48 L.Ed.2d 338 (1976) (quoting *Poller v. Colombia Broadcasting,* 368 U.S. 464, 473, 82 S.Ct. 486, 7 L.Ed.2d 458 (1962)). "The liberal approach to the consideration of antitrust complaints is important because inherent in such an action is the fact that all details and specific facts relied upon cannot properly be set forth as part of the pleadings." *See Lucas Indus. v. Kendiesel, Inc.,* 1995 WL 350050, at *2 (D.N.J. June 9, 1995). This court must take "mere conclusions of the pleader" into account when deciding whether a claim for relief is stated. *See id.* at *2 (quoting *United States v. Employing Plasterers' Assn.,* 347 U.S. 186, 188 (1954)).

However, courts have determined that "the heavy costs of modern federal litigation, especially antitrust litigation, and the mounting caseload pressure on the federal courts," militate in favor of requiring some reasonable particularity in pleading violations of the federal antitrust laws." *See Sutliff, Inc. v. Donovan, Co.,* 727 F.2d 648, 654 (7th Cir.1984); *Garshman v. Universal Resources Holding, Inc.,* 641 F.Supp. 1359, 1367 (D.N.J.1986).

DISCUSSION

Warner-Lambert argues that Purepac's counterclaims of antitrust violation should be dismissed for failure to state a claim because Warner-Lambert's claims of patent infringement are protected under the *Noerr-Pennington* doctrine. Furthermore, Warner-Lambert argues that Purepac lacks standing to bring a claim for antitrust injury.

A. Immunity under Noerr-Pennington Doctrine

1. Sham Litigation

***5** Purepac claims that Warner-Lambert initiated patent infringement litigation for the sole purpose of forestalling Purepac's ability to enter the gabapentin market. Warner-Lambert claims protection under the *Noerr-Pennington* doctrine of immunity for activities petitioning the government, including access to the courts for redress of grievances. *See* Eastern R.R. President Conference v. Noerr Motor Freight, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961). Under this doctrine, Warner-Lambert would be immune from antitrust liability for the anti-competitive effects of its patent infringement litigation. *See* Professional Real Estate Investors, et. al. v. Columbia Pictures Indus., Inc., et. al., 508 U.S. 49, 60, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993). However, there is an exception to this immunity when the patent infringement case is considered "sham" litigation, i.e. instituted for the sole purpose of precluding competition.

The Supreme Court has established the following test for "sham" litigation:
First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr,* and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor.'

Id. at 60-61 (quoting Noerr, 365 U.S. at 144).

Warner-Lambert argues that, as a matter of law, a patent infringement suit which survives summary judgment cannot be considered "objectively baseless" within the meaning of the "sham" litigation test. Warner-Lambert relies on *Harris Custom Builders, Inc. v. Hoffmeyer,* 834 F.Supp. 246, 261-62 (N.D.Ill.1993), which held that "[a]n action that is well grounded, factually and legally, to survive a summary judgment is sufficiently meritorious to lead a reasonable litigant to conclude that they had some chance of success on the merits." *Id. Harris Custom Builders* dealt with a case in which summary judgment of non-infringement was denied.

In this case, Warner-Lambert's claims survived summary judgment in the 98-2749 patent infringement action based on Purepac's application for generic gabapentin capsules. Purepac's antitrust counterclaims in 99-5984 are based on the capsule litigation in 98-2749, in combination with the infringement litigation (99-5948) brought by Warner-Lambert after Purepac's application to market generic gabapentin tablets. Therefore, the denial of summary judgment in 98-2749 does not necessarily relate to the asserted basis for antitrust relief.

Moreover, denial of summary judgment denial, in and of itself, cannot deem litigation objectively reasonable without specific examination of the basis for denial of summary judgment. *See* Filmtech Corp. v. Hydranautics, 67 F.3d 931, 938 (Fed.Cir.1995) (citing Boulware v. Nevada Dep't of Human Resources, 960 F.2d 793, 798-99 (9th Cir.1992) ("a preliminary success on the merits does not preclude a court from concluding that litigation was baseless"). This Court's August 25, 1999 order denying summary judgment was based in part on unresolved discovery issues involving the '476 patent infringement claim. Consequently, the order, by itself, does not require a finding that Warner-Lambert's 98-2749 litigation was reasonably calculated to elicit a favorable outcome.

***6** As to the '479 patent infringement claim, this Court found that there was sufficient evidence to "create a genuine issue of material fact as to whether Purepac will knowingly and actively induce infringement of Patent '479." The '479 patent claims the use of gabapentin for treatment of neuro-degenerative diseases. However, the record indicates that this is an "off-label" use for Neurontin because the FDA has not approved Neurontin for treatment of neuro-degenerative diseases. Purepac's ANDA for a generic form of gabapentin only claims the method of use for treatment of epilepsy. Consequently, Purepac

alleges that Warner-Lambert's claim of '479 patent infringement is merely a "sham" to disguise the anti-competitive goal of preventing Purepac from receiving FDA approval of their ANDA. The mere fact that summary judgment was denied in the 98-2749 litigation does not, in and of itself, preclude Purepac's counterclaims of antitrust violations.

2. Fraudulent Conduct

Purepac further claims that Warner-Lambert does not enjoy *Noerr-Pennington* immunity because Warner-Lambert fraudulently listed Patents '476 and '479 in the Neurontin NDA, which automatically triggered the FDA listing of both patents in the Orange Book. According to Purepac, any generic gabapentin manufacturer is prevented from applying for an ANDA without listing the patents contained in the Orange Book and giving notice to the patent holder, thereby triggering infringement litigation. Under the Hatch-Waxman Act, once a pioneer manufacturer has filed an infringement claim, approval of the generic manufacturer's ANDA is stayed for a period prescribed in 21 U.S.C. 355(c)(3)(C). Purepac argues that Warner-Lambert's fraudulent listing of the '476 and '479 patents in the NDA precluded Purepac's ability to compete in the market.

A counterclaim alleging that a patent infringement plaintiff "obtained patent by knowingly and willfully misrepresenting the facts" will "be sufficient to strip [the plaintiff] of its exemption from the antitrust liability." *Walker Process Equip., Inc. v. Food Machinery and Chemical Corp.*, 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965). Historically, while regional law has always been applied to antitrust litigation, the Federal Circuit has held that "whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from antitrust law is to be decided as a question of Federal Circuit Law." *Nobelpharma v. Implant Innovations*, 141 F.3d 1059, 1067-68 (Fed.Cir.1998).

Warner-Lambert first argues that Purepac incorrectly implicates the fraud exception to *Noerr* because Purepac did not sufficiently allege fraud in the counterclaim. Purepac did not explicitly mention the word "fraud." However, in *Nobelpharma* the Federal Circuit defined the fraud exception to *Noerr-Pennington* immunity as "a knowing, willful and intentional act, misrepresentation, or omission." *Nobelpharma*, 141 F.3d at 1070. Purepac alleges that "Warner Lambert caused the '476 patent to be listed in the Orange Book knowing that it does not cover gabapentin sold under the trade name Neurontin ... Warner-Lambert improperly caused the '476 patent to be listed in the Orange Book. Warner Lambert's motive and intent in causing the '476 patent to be listed in the Orange Book was to forestall competition in the market for Gabapentin." *See* Answer and Counterclaim. ¶ 63-64. Purepac makes the same assertions regarding the '479 patent. *See* Answer and Counterclaim, ¶ 66-67. Purepac adequately alleges that Warner-Lambert knowingly made misrepresentations to the FDA with the specific intent to prevent competition.

***7** Warner-Lambert next argues that Purepac does not apply the current law. Warner-Lambert cites *Armstrong Surgical Center, Inc. v. Armstrong County Mem. Hosp.*, 185 F.3d 154, 162 (3rd Cir.1999). *cert. denied*, 530 U.S. 1261, 120 S.Ct. 2716, 147 L.Ed.2d 982 (U.S. June 26, 2000) for the proposition that "liability for injuries caused by state action is precluded even where the action did so by bribery, deceit or other wrongful conduct that may have affected the decision making process." Warner-Lambert argues that even if it was fraudulent in listing the '476 and '479 patents, it is protected from antitrust liability because the FDA, as a state actor, controls the Orange Book and requirements for ANDA applicants.

However, the *Armstrong* case does not apply to this matter. Although *Armstrong* involves a private party who deceived a state department, the department also conducted independent investigations and provided for two separate reviews of the decision. *See id.* at 163. This differs from a situation where the alleged deceit and fraudulent conduct is directed at a regulatory agency which does not conduct independent investigations. Consequently, the *Armstrong* court drew a distinction from a typical patent case:

The decision making process [in a typical patent situation] was an ex parte one in which the Patent Office was wholly dependent on the applicant for the facts. While the Patent Office can determine the prior act from its own records, it effectively and necessarily delegates to the applicant the factual determinations underlying the issuance of a patent. Accordingly, when the applicant has submitted false factual information, the state action is dependent on financially interested decision making.

Id. at 164.

In this case, Purepac contends that the FDA relies solely upon the NDA applicant's information when

listing patents in the Orange Book. *See* Answer and Counterclaim ¶ 47. Therefore, the FDA would be forced to rely upon fraudulent misrepresentations by Warner-Lambert. Viewing the allegations in the counterclaim in the light most favorable to Purepac, discovery could demonstrate fraudulent conduct by Warner-Lambert, thereby removing immunity from antitrust liability.

B. Antitrust Standing

Warner-Lambert argues that Purepac's counterclaims for violations of the Sherman Act must be dismissed because Purepac does not have standing to assert antitrust injury. The United Supreme Court has listed the appropriate guidelines for determining whether antitrust standing exists. *See* Associated Gen. Contractors v. California State Council of Carpenters, 459 U.S. 519, 534-45, 103 S.Ct. 897, 74 L.Ed.2d 723 (1983). This Court must decide:
(1) whether there is a causal connection between an antitrust violation and harm to the plaintiff and the defendants intended to cause that harm;
(2) whether the nature of the plaintiff's alleged injury was of the type the antitrust laws were intended to forestall;
(3) the directness or indirectness of the asserted injury;
***8** (4) whether the claim rests on some abstract or speculative measure of harm; and
(5) the strong interest in keeping the scope of complex antitrust trials within judicially manageable limits, avoiding both duplicative recoveries and the complex apportionment of damages.

See Indium Corp. of America v. Semi-Alloys, Inc., 781 F.2d 879, 882 (Fed.Cir.1985) (quoting *Associated Gen. Contractors,* 459 U.S. at 434-45).

These general guidelines have been supplemented by caselaw which focuses on the direct issue in this matter. The specific rules under 21 U.S.C. § 355(j)(5)(B)(iii) ("Hatch-Waxman Act") require a thirty-month stay on FDA approval for a generic pharmaceutical manufacturer's ANDA when the ANDA product becomes involved in patent infringement litigation with the pioneer manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Because "the commencement of litigation automatically delay[s] FDA approval of the generics' proposed drugs." the patent infringement plaintiff has the power to forestall a generic manufacturer's ability to market a product. *See* Bristol-Meyers v. Ben Venue Lab., 90 F.Supp.2d 540, 544 (D.N.J.2000). Therefore, the generic manufacturer's injury does not merely result from the "structure of a regulated industry," but from the decision of the pioneer manufacturer to bring suit. *See* id. at 545. Consequently, the Supreme Court's requirement for a special "causal connection" and "directness" of injury must be liberally construed when dealing with regulatory conditions under the Hatch-Waxman Act.

In this case. Warner-Lambert instituted the patent infringement cases against Purepac. thereby delaying FDA approval of a generic form of gabapentin in either tablet or capsule form. This decision to delay approval of the ANDA was not left to the discretion of the FDA, so it cannot be attributed to the structure of the regulated industry. Warner-Lambert has exercised its power under Hatch-Waxman to temporarily foreclose Purepac's access to the market for gabapentin. Purepac has alleged a sufficient causal connection between Warner-Lambert's allegedly fraudulent conduct and Purepac's injuries.

Accordingly, this Court finds that Purepac has standing to bring antitrust counterclaims against Warner-Lambert.

II. Warner-Lambert's Motion for Partial Summary Judgment Against Purepac's Unfair Competition Counterclaim, or in the Alternative, Bifurcation of the Patent and Antitrust Claims in Docket No. 98-02749.

STANDARD OF REVIEW

Summary judgment eliminates unfounded claims without recourse to a costly and lengthy trial. *See* Celotex Corp. v. Catrett, 477 U.S. 317, 327, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). However, a court should grant summary judgment only "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). The burden of showing that no genuine issue of material fact exists rests initially on the moving party. *See* Celotex, 477 U.S. at 323. A litigant may discharge this burden by exposing "the absence of evidence to support the nonmoving party's case." Id. at 325. In evaluating a summary judgment motion, a court must view all evidence in the light most favorable to the nonmoving party. *See* Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S.

574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986); *Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir.1976).

***9** Once the moving party has made a properly supported motion for summary judgment, the burden shifts to the nonmoving party to "set forth specific facts showing that there is a genuine issue for trial ." *Fed.R.Civ.P.* 56(e); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). The substantive law determines which facts are material. *Id.* at 248. "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Id.* No issue for trial exists unless the nonmoving party can demonstrate sufficient evidence favoring it such that a reasonable jury could return a verdict in that party's favor. *See id.* at 249.

DISCUSSION

A. Partial Summary Judgment

Warner-Lambert moves for summary judgment dismissing Purepac's unfair competition counterclaim. Warner-Lambert makes three arguments in support of summary judgment: A) New Jersey unfair competition claims only encompass the illegal "passing off" of a competitor's product as one's own product. B) Warner-Lambert's patent infringement suits against Purepac are protected under the *Noerr-Pennington* immunity doctrine, and C) Purepac does not have standing to bring the unfair competition claims because Purepac has suffered no injury.

In Part I of this opinion, the Court addressed Warner-Lambert's arguments regarding immunity under *Noerr-Pennington* and Purepac's alleged lack of standing. Warner-Lambert's brief admits the identical nature of the arguments:
In light of the substantial overlap of issues relating to defendants' unfair competition counterclaim in this action and their antitrust and unfair competition counterclaim in [99-5948: capsule litigation], the discussion in Sections B and C [dealing with *Noerr-Pennington* and standing], *infra,* and in Warner-Lambert's memorandum in support of its Fed.R.Civ.P. 12(b)(6) motion to dismiss defendants' antitrust and unfair competition counterclaims in [99-5948: capsule litigation] is *essentially the same.* *Warner-Lambert's Brief* at p.12 n. 2. Therefore, this Court will only address Warner-Lambert's first argument which addresses the scope of the New Jersey unfair competition claim.

Warner-Lambert argues that the New Jersey law of unfair competition is limited to the "passing-off" of one's goods as those of a competitor and similar deceptive practices. However, caselaw demonstrates that the unfair competition claim is not as narrow as Warner-Lambert contends.

Warner-Lambert relies on a district court decision which states that "under New Jersey common law, unfair competition encompasses two separate torts: (1) passing off one's goods or services as those of another; and (2) unprivileged imitation." *See Eli Lilly & Co. v. Russel Corp.*, 23 F.Supp.2d 460, 494 (D.N.J.1998). Warner-Lambert argues that Purepac's allegations of unfair competition do not fit into either category because Purepac's allegations are based only on sham litigation and fraudulent submissions of patent information to the FDA.

***10** The Court is inclined to follow the cases relied upon by Purepac. *See Biovail Corp. Int'l v. Aktiengesellschaft*, 49 F.Supp.2d 750 (D.N.J.1999); *Duffy v. Charles Schwab & Co., Inc.*, 97 F.Supp.2d 592 (D.N.J.2000). In *Biovail,* Judge Barry denied the defendants' motion to dismiss plaintiff's claims of unfair competition under New Jersey law because the conduct alleged was "injurious and otherwise unfair, improper and wrongful" and "having found that the conduct alleged by [plaintiff] constitutes, at least on the pleadings, possible antitrust violations, it is fair to say that the conduct states a claim under the much broader common law tort of unfair competition." *Biovail,* 49 F.Supp.2d at 777. In *Duffy,* Judge Cooper emphasized that although the defendant argued that the *Eli Lilly* case stood for the proposition that "only two types of claims may be brought under New Jersey's unfair competition law: (1) passing off, and (2) unprivileged imitation .... [t]he language of *SK & F* and *Eli Lilly* should not be read to limit the reach of New Jersey's unfair competition law to these two torts alone." *Duffy,* 97 F.Supp.2d at 601 n. 8. Accordingly, this Court rejects Warner-Lambert's argument that caselaw narrows the scope of unfair competition claims.

The Restatement (Third) of Unfair Competition suggests a broad range of unfair competition claims:
Certain recurring patterns of objectionable practices form the basis of the traditional categories of liability specifically enumerated in [the Restatement].

However, *these specific forms of unfair competition do not fully exhaust the scope of statutory or common law liability for unfair methods of competition* .... It is impossible to state a definitive test for determining which methods of competition will be deemed unfair in addition to those included in the categories of conduct described in the preceding Comments. Courts continue to evaluate competitive practices against generalized standards of fairness and social utility. *Judicial formulations have broadly appealed to principles of honesty and fair dealing, rules of fair play and good conscience, and the morality of the marketplace.* The case law, however, is far more circumscribed than such rhetoric might indicate, and courts have generally been reluctant to interfere in the competitive process. An act or practice is likely to be judged unfair only if it substantially interferes with the ability of others to compete on the merits of their products or otherwise conflicts with accepted principles of public policy recognized by statute or common law.

RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 1 cmt. g (1995) (emphasis added). In fact, the comments to the Restatement state that unfair competition claims also apply to "one who interferes by instituting or threatening to institute groundless litigation against a competitor." *Id.* The Restatement explains that the somewhat narrow interpretation of unfair competition claims by caselaw is that "an act or practice is likely to be judged unfair only if it substantially interferes with the ability of others to compete on the merits of their products."

***11** In this case, Purepac alleges Warner-Lambert's conduct has prevented the marketing of a generic form of gabapentin, thereby interfering with Purepac's ability to compete on the merits of the product described in its ANDA. The Court disagrees. Purepac's allegation of fraudulent submissions to the FDA falls within the scope of the unfair competition claims as defined by caselaw and the Restatement. Accordingly, this Court is unwilling to dismiss Purepac's counterclaims based solely on Warner-Lambert's narrow interpretation of New Jersey unfair competition law.

B. Bifurcation

As an alternative to dismissal, Warner-Lambert seeks the bifurcation of the patent claims from the unfair competition claims. Under the Federal Rules of Civil Procedure,

> The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim, cross-claim, counterclaim, or third-party claim, or of any separate issue or of any number of claims, cross-claims, counterclaims, third-party claims, or issues, always preserving inviolate the right of trial by jury as declared by the Seventh Amendment to the Constitution or as given by a statute of the United States.

FED. R. CIV. P. 42(b). Generally, "[u]nder Rule 42(b), a district court has broad discretion in separating issues and claims for trial as part of its wide discretion in trial management." *Gardco Manufacturing, Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1212 (Fed.Cir.1987). The Federal Circuit has approved the "standard practice of separating for trial patent issues and those raised in an antitrust counterclaim." *In re Innotron Diagnostics*, 800 F.2d 1077, 1084 (Fed.Cir.1986); *see also Virginia Panel Corp. v. Mac Panel Co.*, 887 F.Supp. 880, 883-84 (W.D.Va.1995), *aff'd*, 133 F.3d 860 (Fed.Cir.1997); *Hunter Douglas Inc. v. Comfort Corp.*, 44 F.Supp.2d 145, 148 (N.D.N.Y.1999) (finding that the effort "to protect the property rights granted vis-a-vis the patent ... may be viewed as an attempt to extend them, temporally or otherwise, beyond the bounds set by the patent statute ... that allegedly runs afoul of the antitrust laws); *Alarm Device Mfg. Co. v. Alarm Products Intern., Inc.*, 60 F.R.D. 199, 202 (E.D.N.Y.1973) ("More often than not, separate trials of patent validity-infringement claims and misuse-antitrust claims have been found to be salutary"); *Brandt, Inc. v. Crane*, 97 F.R.D. 707, 708 (N.D.Ill.1983) (adopting the "general rule" that separating patent and antitrust issues serves the purposes of convenience, expedience, and economy).

The Federal Circuit has emphasized the necessity of bifurcation of antitrust claims and patent infringement claims because it "will enhance the parties' right to jury trial by making the issues the jury must consider less complex." *See Innotron*, 800 F.2d at 1086. When deciding a motion to bifurcate, the court should consider "whether one trial or separate trials will best serve the convenience of the parties and the court, avoid prejudice, and minimize expense and delay [and] the major consideration is directed toward the choice most likely to result in a just final disposition of the litigation." *Id.* at 1084.

***12** Purepac argues that bifurcation is inappropriate because "there will be substantial overlap between the issues relevant to the patent and unfair

competition claims" based on allegations of Warner-Lambert's fraudulent statements to the FDA and sham litigation. This is probably true. However, caselaw indicates that such overlap supports bifurcation. *See Innotron,* 800 F.2d 1085 (holding that bifurcation was appropriate because defendant's affirmative defenses to the patent infringement case were identical to the antitrust counterclaims and therefore, "if [defendant] prevails at the trial on its affirmative defenses it need not again prove the same issues at the antitrust trial." In *Hunter,* the defendant in a patent infringement case brought antitrust counterclaims against the plaintiff alleging sham litigation. The court ordered bifurcation based on the following analysis:

if [plaintiff] succeeds in its patent infringement action, a significant portion of [defendant's] proof relative to its § 2 [Sherman Act] claim would become irrelevant. This could significantly shorten presentation of [defendant's] antitrust counterclaims. Likewise, during the patent infringement suit, [defendant] would have an opportunity to present its defenses of patent invalidity and inequitable conduct. Resolution of these issues would become the law of the case and also eliminate some of the proof that would otherwise be necessary. Accordingly, the interest of judicial efficiency favors separating the patent issues from those grounded on antitrust principles.

Hunter, 44 F.Supp.2d at 152.

In this case, Purepac's antitrust claims based on sham litigation will be addressed during the patent infringement trial because the outcome of that trial may either support or eliminate Purepac's claim that Warner-Lambert filed an objectively baseless suit.

Purepac also contends that the unfair competition claim based on Warner-Lambert's allegedly fraudulent submission to the FDA, which caused an automatic stay of Purepac's ANDA approval, will be viable regardless of the outcome of the patent infringement trial. However, the patent infringement trial will resolve the scope of the '476 and '479 patents, which is relevant to a determination of whether Warner-Lambert could have engaged in inequitable conduct by listing the patents in the NDA for Neurontin.

Although Purepac relies on a few district court cases denying bifurcation, this Court finds that they are distinguishable. *See ACS Communications, Inc. v. Plantronics, Inc.,* 1995 WL 743726 (N.D.Cal. Dec.1, 1995) (denying bifurcation because the antitrust claim was filed before the patent infringement counterclaim); *General Tel. & Elec. Labs. Inc. v. National Video Corp.,* 297 F.Supp. 981 (N.D.Ill.1968) (denying bifurcation of all counterclaims in a patent infringement case involving counterclaims which alleged *both* antitrust violations *and* new patent infringement claims); *Spectra-Physics Lasers. Inc. v. Uniphase Corp.,* 144 F.R.D. 99 (N.D.Cal.1992) (denying bifurcation of issues of liability and damages).

***13** Therefore, this Court concludes that bifurcation would best serve the interests of justice.

III. Warner-Lambert's Motion to Dismiss Purepac's Complaint Seeking Declaratory Judgment of Non-Infringement under Rule 12(b)(1) and Rule 12(b)(6) in Docket No. 00-02053.

STANDARD OF REVIEW

A defendant may challenge the court's subject matter jurisdiction in two ways. First, defendant may attack the jurisdictional allegations of a complaint on its face. *See Cardio-Medical Ass'n Ltd. v. Crozer-Chester Med. Ctr.,* 721 F.2d 68, 75 (3d Cir.1983) (commenting that the Court in assessing a Rule 12(b)(1) motion based on [a facial jurisdictional attack] on the pleadings must assume that the allegations contained in the complaint are true and holding that allegations in complaint were sufficient to meet jurisdictional requirement of Sherman Act) (citations omitted). The second way to bring a 12(b)(1) motion is a factual jurisdictional attack, in which case the Court may rely on competent evidence other than the complaint. *See Land v. Dollar,* 330 U.S. 731, 735 n. 4, 67 S.Ct. 1009, 91 L.Ed. 1209 (1947) (noting that "when a question of the District Court's jurisdiction is raised, ... the court may inquire by affidavits or otherwise, into the facts as they exist").

Therefore, unlike a 12(b)(6) motion, in considering a 12(b)(1) motion based on a factual jurisdictional attack to a complaint, "no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims. Moreover, [in defending against a factual jurisdictional attack], the plaintiff will have the burden of proof that jurisdiction does in fact exist." *Mortensen v. First Fed. Savings & Loan Ass'n,* 549 F.2d 884, 891 (3d Cir.1997) (vacating

dismissal of Sherman Act claim for lack of subject matter jurisdiction and finding that "a combination of the timing of the factual jurisdictional attack, the plaintiff's having the burden of proof, and the court's having a free hand in evaluating jurisdictional evidence ... can unfairly preclude Sherman Act plaintiffs from reaching the merits of their cases"); Lang v. Rubin, 73 F.Supp.2d 448, 450 (D.N.J.1999). "That the district court is free to determine facts relevant to its jurisdiction has long been clear." Mortensen, 549 F.2d at 891 n. 16 (citing Wetmore v. Rymer, 169 U.S. 115, 18 S.Ct. 293, 42 L.Ed. 682 (1898)). "[D]ismissal for lack of subject matter jurisdiction is not appropriate merely because the legal theory alleged is probably false, but only because the right claimed is 'so insubstantial, implausible, foreclosed by prior decisions of this Court, or otherwise completely devoid of merit as not to involve a federal controversy.' " Growth Horizons, Inc. v. Delaware County, Pa., 983 F.2d 1277, 1280-81 (3d Cir.1993) (reversing dismissal for lack of subject matter jurisdiction on Fair Housing Act claim) (quotation omitted). "The threshold to withstand a motion to dismiss under Fed.R.Civ.P. 12(b)(1) is thus lower than that required to withstand a Rule 12(b)(6) motion." Lunderstadt v. Colafella, 885 F.2d 66, 70 (3d Cir.1989) (quotation omitted).

DISCUSSION

1. Rule 12(b)(1) Motion to Dismiss for Lack of Subject Matter Jurisdiction

***14** Warner-Lambert argues that Purepac has violated the Declaratory Judgment Act by filing the instant complaint as a mere pre-emptive strategy to avoid the statutory provisions of the Hatch-Waxman Act.

The Declaratory Judgment Act provides:
[i]n a case of actual controversy within its jurisdiction, except with respect to Federal taxes ..., any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewed as such.

§ 28 U.S.C. 2201.

The Federal Circuit has set standards regarding jurisdiction of declaratory judgment claims against a patentee. *See* Fina Research v. Baroid Ltd., 141 F.3d 1479, 1481 (Fed.Cir.1998); Genentech, Inc. v. Eli Lilly & Co., 998 F.2d 931, 936-37 (Fed.Cir.1993). "We regularly review whether there is jurisdiction over an action seeking a declaratory judgment." Fina, 141 F.3d at 1481; *see generally* Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1058-59 (Fed.Cir.1995). In *Fina,* the Federal Circuit held:
[t]o determine whether there is an actual controversy in declaratory judgment actions involving allegations of patent non-infringement, invalidity, or unenforceability, we apply a two-prong inquiry: There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

Fina, 141 F.3d at 1481 (citing Super Sack, 57 F.3d at 1058 (quoting BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed.Cir.1993)). *See also* Genentech, 998 F.2d at 936-37. Although the court has discretion to decide whether subject matter jurisdiction exists, "the exercise of discretion in [deciding to entertain] a declaratory judgment must have a basis in sound reason" and conform to the established rule. Genentech, 998 F.2d at 936.

A. The Hatch-Waxman Act

The Hatch-Waxman Act was enacted to regulate the interplay between pioneer drug manufacturers and generic drug manufacturers. When filing an NDA, the pioneer applicant must file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted. *See* 21 U.S.C. 355(b)(1). Upon approval of the NDA, any claimed patents for the approved drug are published in the Orange Book. *See* 21 U.S.C. 355(j)(7)(A)(iii).

A generic manufacturer of the original drug approved by the NDA must file an ANDA with the FDA. The ANDA applicant must also certify as part of the application that for each patent listed: (I) such patent information has not been already filed; (II) such patent has expired; (III) the date on which such patent

will expire; or (IV) such patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. *See* 21 U.S.C. 355(j)(2)(A)(vii). An ANDA applicant making a Paragraph IV certification must provide notice to the owner of the patent and the holder of the approved NDA for the listed drug, stating that it has submitted an ANDA and including a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." § 21 U.S.C. 355(j)(2)(B)(ii). Furthermore, a Paragraph IV certification creates a cause of action for patent infringement. If, within 45 days of receiving notice, the patent owner sues the ANDA applicant for patent infringement, the ANDA approval is essentially stayed for 30 months. *See* 21 U.S.C. 355(j)(5)(B)(iii).

***15** The statute also provides that during the 45-day period after the ANDA applicant gives notice of its Paragraph IV certification, "no action may be brought under section 2201 of Title 28 for a declaratory judgment with respect to the patent." § 21 U.S.C. 355(j)(5)(B)(iii)(III).

The legislative history of the Hatch-Waxman Act states that:
No action for a declaratory judgment regarding the patent at issue may be brought before the expiration of the 45 day period commencing with the provision of notice of the certification of patent invalidity or non-infringement. After the 45 day period, any suit for declaratory judgment regarding the patent at issue must be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

H.R. Rep. 98-857(I), 98th Cong., 2ND Sess.1984. at 47.

The purpose of the forty-five day period is to provide the patentee time in which to bring suit for patent infringement. Although the legislative history allows for a declaratory judgment action after the forty-five day period, there is no indication that Congress meant to permit the alleged infringer to bring a declaratory judgment action before the commencement of the forty-five day period.

Purepac contends that the forty-five day period during which a declaratory judgment action is prohibited did not commence until Purepac filed the Paragraph IV certification and notice. Because the FDA was late in filing the '482 patent in the "Orange Book." Purepac did not know whether it was necessary to file the Paragraph IV certification for two weeks. Before that two-week period expired, and before Purepac filed its Paragraph IV certification. Purepac brought suit for declaratory judgment against Warner-Lambert. This Court rejects Purepac's argument that its declaratory judgment action is permitted.

The record indicates that Warner-Lambert filed Patent '482 with the FDA (for purposes of listing in the Orange Book) immediately after receiving approval from the U.S. Patent Office on April 25, 2000. Purepac claims that the '482 patent was not listed in the Orange Book until May 16, 2000. However, any delay in the actual listing of patents in the Orange Book is not attributable to Warner-Lambert because the FDA controls the Orange Book. This Court is not in a position to modify the clear intent of the Hatch-Waxman Act because of delays attributable to the FDA's clerical system. 21 U.S.C. 355(j)(5)(B)(iii)(III) is meant to give the patentee a limited period of time to decide whether to bring suit for infringement before a declaratory judgment action can be instituted by a generic drug manufacturer.

In this case, Warner-Lambert was issued the '482 patent on April 25, 2000 and Warner-Lambert submitted the patent information to the FDA on that same day. Purepac became aware of the '482 patent and Purepac filed a declaratory judgment action on April 28, 2000. Purepac alleges that the action was properly filed because the '482 patent had not yet been listed in the Orange Book. Purepac did not amend their generic gabapentin ANDA until after May 16, 2000 and Warner-Lambert did not receive Purepac's Paragraph IV certification until June 14, 2000.

***16** After review of the Hatch-Waxman Act, this Court finds that Congress' dominant intent was to create a thirty-month period during which a pioneer manufacturer could be free from generic competition if it started suit to determine whether a generic manufacturer has infringed an existing patent. This period is triggered by the filing of infringement litigation by the pioneer manufacturer. The suit itself is triggered by the Paragraph IV certification and notice submitted by the generic manufacturer. Once a Paragraph IV certification is made, a suit seeking a declaratory judgment of non-infringement and/or invalidity should be discontinued. Congress' secondary intent under the Hatch-Waxman Act was to establish a sequential series of events based on the assumption that the following would occur in this order: patent, NDA. ANDA and Paragraph IV certification. However, the facts in this case did not

occur in the temporal sequence assumed by the Hatch-Waxman Act. In choosing which Congressional intent to enforce, this Court chooses the broader intent because the thirty-month moratorium is more critical to the Congressional scheme than the procedural sequence of events. The Court further notes that infringement litigation has already commenced on the '482 patent. Accordingly, the appropriate resolution is to dismiss the declaratory judgment action.

Caselaw offers minimal guidance as to whether generic drug companies can file declaratory judgment claims before the FDA lists the patent in the Orange Book. Both Purepac and Warner Lambert rely on different theories espoused in *Ben Venue Lab., Inc. v. Novartis Pharm. Corp.*, 10 F.Supp.2d 446, 451-52, (denying a motion to dismiss complaint for lack of subject matter jurisdiction). In *Ben-Venue,* the alleged infringing plaintiff filed a claim seeking a declaratory judgment that one of the defendant's patents was improperly listed in the Orange Book because the defendant deceived the FDA. Although this claim was filed during the forty-five day period set forth in the Hatch-Waxman Act, the court permitted the claim. The court reasoned that 21 U.S.C. 355(j)(5)(B)(iii)(III) "is limited to declaratory judgment actions ... aimed solely at the narrow patent issues of infringement and invalidity." *Id.* at 451.

In this case, Purepac seeks a declaratory judgment that Warner-Lambert's '482 patent is invalid and Purepac's generic form of gabapentin does not infringe. This is the exact type of claim that the Hatch-Waxman Act prohibits before the expiration of the forty-five day period.

The Federal Circuit has offered some guidance in the construction of the Hatch-Waxman Act in *DuPont Merck Pharm. Co. v. Bristol-Meyers Squibb Co.*, 894 F.Supp. 804 (D.Del.1995), *aff'd* 62 F.3d 1397 (Fed.Cir.1995). In *DuPont,* the Federal Circuit affirmed the lower court's dismissal of plaintiff's complaint seeking a declaratory judgment of patent invalidity and non-infringement. The plaintiff, a generic drug manufacturer, had not filed a Paragraph IV certification or given notice to defendant regarding patents which had an extended expiration date due to the Uruguay Round Agreement Acts ("URAA"). The lower court held that "an actual controversy for purposes of the Declaratory Judgment Act will only occur upon the filing of the appropriate paragraph IV certification by [plaintiff] with the FDA." *See Dupont,* 894 F.Supp. at 809. In affirming this decision, the Federal Circuit held that the special protections of the URAA did not insulate an alleged patent infringer from following the necessary steps under 21 U.S.C. 355(j)(5)(B)(iii)(III). *See id.*

***17** Similar to the *DuPont* court's reasoning, this Court is not prepared to let the filing methods of the FDA interfere with the purpose and intent of the Hatch-Waxman Act.

B. The First-Filed Rule

Purepac argues that this Court cannot dismiss its suit for declaratory judgment by application of the first-filed rule. The Court of Appeals for the Third Circuit has adopted the "first-filed rule" which applies to parallel cases filed in separate district courts. *See EEOC v. University of Pa.*, 850 F.2d 969, 971 (3d. Cir.1988); *Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925, 929 (3d Cir.1941), *cert. denied.* 315 U.S. 813, 62 S.Ct. 798, 86 L.Ed. 1211 (1942). "In all cases of federal concurrent jurisdiction, the court which first has possession of the subject must decide it." *Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925, 929 (3d Cir.1941) (quoting *Smith v. McIver,* 22 U.S. (9 Wheat.) 532, 6 L.Ed. 152 (1824)), *cert. denied,* 315 U.S. 813, 62 S.Ct. 798, 86 L.Ed. 1211 (1942). Consequently, trial judges may exercise their discretion to enjoin subsequent prosecution of "similar cases ... in different federal district courts." *EEOC,* 850 F.2d at 971.

Although the first-filed rule gives the trial court broad discretion. Third Circuit precedent has established certain exceptions to the application of the rule, including forum-shopping, bad faith, and inequitable conduct. *See EEOC,* 850 F.2d at 971. "We emphasize, however, that invocation of the rule will usually be the norm, not the exception. Courts must be presented with exceptional circumstances before exercising their discretion to depart from the first-filed rule." *Id.* at 979.

Purepac relies on *Genentech Inc. v. Eli Lilly & Co.*, 998 F.2d 931 (Fed.Cir.1993), where the court applied the first-filed rule to patent litigation and rejected the reasoning of *Tempco v. Electric Heater Corp. v. Omega Eng'g Inc.*, 819 F.2d 746 (7th Cir.1987) (holding that the first-filed rule does not apply to trademark cases). In applying the first-file rule to patent litigation, the *Genentech* court gave the following rationale:

[s]uch a rule [in *Tempco*] would automatically grant the patentee the choice of forum, whether the

patentee had sought-or sought to avoid-judicial resolution of the controversy. This shift of relationship between litigants is contrary to the purpose of the Declaratory Judgment Act to enable a person caught in controversy to obtain resolution of the dispute, instead of being forced to await the initiative of the antagonist.... We prefer to apply in patent cases the general rule whereby the forum of the first-filed case is favored, unless considerations of judicial and litigant economy, and the just and effective disposition of disputes, require otherwise.

Id. at 937. In relation to patent cases, the first-filed rule is used only as protection against a patentee's ability to forum-shop. However, in this case the suit for declaratory judgment and the litigation of patent infringement claims are reciprocal cases which are both filed in this Court. Therefore, forum selection is not an issue.

***18** Moreover, the *Genentech* decision differs from the immediate case because the *Genentech* decision dealt with DNA technology which was not subject to FDA regulations. Therefore, in *Genentech,* there was no statutory regulation analogous to the Hatch-Waxman Act which prohibited suit. Accordingly, this Court finds that subject matter jurisdiction is lacking over Purepac's claim for a declaratory judgment.

2. Motion to Dismiss for Failure to State a Claim

Warner-Lambert seeks to dismiss Purepac's complaint for failure to state a claim. Because this Court holds that subject matter jurisdiction is lacking over Purepac's declaratory judgment complaint, due to the Hatch-Waxman Act. Warner Lambert's 12(b)(6) motion to dismiss the complaint need not be addressed.

I. Docket No. 99-05948

For the reasons set forth in the accompanying opinion IT IS on this *22nd* day of December, 2000 ORDERED that Warner Lambert's motion to dismiss Purepac's counterclaims three through five is denied.

II. Docket No. 98-02749

For the reasons set forth in the accompanying opinion IT IS on this *22nd* day of December, 2000 ORDERED that Warner Lambert's motion to dismiss Purepac's counterclaims alleging unfair competition is denied; and it is further

ORDERED that Warner Lambert's motion to bifurcate the patent infringement claims from the unfair competition counterclaims is granted.

III. Docket No. 00-02053

For the reasons set forth in the accompanying opinion IT IS on this *22nd* day of December, 2000 ORDERED that Warner Lambert's motion to dismiss Purepac's complaint seeking a declaratory judgment is granted.

D.N.J.,2000.
Warner Lambert Co. v. Purepac Pharmaceutical Co.
Not Reported in F.Supp.2d, 2000 WL 34213890 (D.N.J.)

Briefs and Other Related Documents (Back to top)

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